



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

91090-3

Date of Issuance:

3/28/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 03/28/2018

Name of Pesticide Product:

Neove Spot On #001 for Dogs

Name and Address of Registrant (include ZIP Code):

Janelle Kay
Shanghai Neway Animal Health Co., Ltd.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

3/28/16

2. This registration is time-limited and expires 03/28/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 91090-3."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/23/2015

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Enclosure

MASTER LABEL: This master label includes label text for different size packages and application rates specific to the pet's age and body weight

{Front Panel}

{Note to Reviewer: The word Dog will be at least 40-75% in height of the largest letter in the primary brand name. A large clear picture of a dog in the respective weight range will be on the front panel of the label. }

Neove Spot On #001 for Dogs

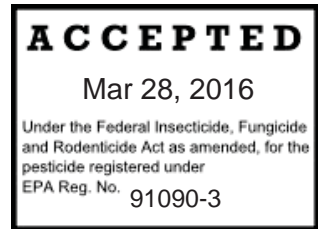
For the Prevention and Treatment of Flea and Lice Infestations on Dogs

Alternate Brand Names

ImidaCare for Dogs [& Puppies]

ImidaStar for Dogs [& Puppies]

PetImida for Dogs [& Puppies]



Once a Month Topical Flea and Lice Treatment

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)

{Picture of a dog in the weight range for the product as packaged will be included in the final labeling}

READ THE ENTIRE LABEL BEFORE EACH USE

{Optional marketing claims follow:}

- [One treatment prevents further flea infestation for at least four weeks]
- [Kills fleas on dogs within 12 hours]
- [Kills fleas before they lay eggs]
- [Convenient, easy to apply]
- [Kills [biting, chewing] lice]
- [For treatment and prevention of [biting, chewing] lice [infestations]]
- [Controls existing [biting, chewing] lice infestations]
- [Dual protection (against fleas and lice)]
- [Treats, prevents and controls [biting, chewing] lice [infestations]]
- [Provides effective control of [biting, chewing] lice [infestations]]
- [Kills [biting, chewing] lice and prevents further infestations]
- [For treatment and prevention of infestations with [biting, chewing] lice]
- [Waterproof]
- [Fragrance free]

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0

{Front Panel, cont.}

EPA Est. No. 091090-XXX-X

EPA Reg. No. 091090 -XXX

NET CONTENTS: [3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR**NET CONTENTS: [3][4][6][8] Tubes each 0.034 fl. oz. (1.0 ml) OR****NET CONTENTS: [3][4][6][8] Tubes each 0.084 fl. oz. (2.5 ml) OR****NET CONTENTS: [3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)**

KEEP OUT OF REACH OF CHILDREN
WARNING

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.

{Note to reviewer: cat icon will be 1.5 cm x 1.5 cm and will appear on the lower right hand corner of the front panel}



{Back Panel}

Once a Month Topical Flea and Lice Treatment	
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)	
OR	
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)	
OR	
For Use only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)	
OR	
For Use only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)	

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
<p>To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency medical treatment information, call 1-800-222-1222.</p> <p>To Physician: Treat the patient symptomatically.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

{Back Panel}

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing 4 – 10 lbs (0.4 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 11 – 20 lbs (1.0 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 21 – 55 lbs (2.5 ml tube)
OR
Use only on dogs 7 weeks and older and weighing Over 55 lbs (4.0 ml tube)
- Do not use on animals other than dogs.
- Do not apply to puppies or dogs under 7 weeks of age and weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do allow the product in the dog's eyes.
- Do not allow children to apply this product.
- Do not allow your dog to ingest this product.
- Do not reapply for 4 weeks.
- Use entire contents of tube on each dog. Do not split one tube between two dogs.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after product has been applied.

[Back Panel]

{Note to reviewer: this box will be located on the lower right hand corner of the back panel}

Side Effects Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

{Note to reviewer: this box will be located on the lower right hand corner of the back panel, below the Side Effects box} DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Icon size 1.5cm x 1.5cm



Manufactured For
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

[Made in China]

Lot No.:

{Insert}

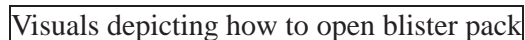
Once a Month Topical Flea and Lice Treatment**For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)****DIRECTIONS FOR USE****READ THE ENTIRE LABEL BEFORE EACH USE**

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as show. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.



3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See “HOW TO OPEN BLISTER PACK”
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the contents directly on the skin. Apply the entire contents of the tube between the shoulder blades of the dog. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.



4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation,

retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for effective control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

{Label on Individual Tube}

Neove Spot On #001 for Dogs

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

Lot No. 0000000

{Label on Blister Pack}

Neove Spot On #001 for Dogs

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

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For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
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[NEWAY]

Lot No. 0000000

[3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR

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[3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)

